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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/759,288 01/16/2004		Marc Elliot Rothenberg	CMC -163	7158	
26875 75	590 09/05/2006	EXAMINER			
WOOD, HERRON & EVANS, LLP			ROONEY, NORA MAUREEN		
2700 CAREW TOWER 441 VINE STREET			ART UNIT	PAPER NUMBER	
CINCINNATI,		1644			

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary			Application No. Applicant(s)						
			10/759,288		ROTHENBERG, MARC ELLIOT				
			Examiner		Art Unit				
			Nora M. Rooney		1644				
Period fo	The MAILING DATE of this communi or Reply	cation appea	ars on the cover sh	eet with the co	orrespondence ad	ldress			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).									
Status									
1) 又	Responsive to communication(s) filed	d on <i>16 Jan</i>	uarv 2004.						
			ction is non-final.						
3)		•—		l matters, pros	secution as to the	e merits is			
. —	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.								
Dispositi	on of Claims								
4)⊠	Claim(s) 1-37 is/are pending in the ap	oplication.							
-	4a) Of the above claim(s) is/are withdrawn from consideration.								
	5) Claim(s) is/are allowed.								
6)	6) Claim(s) is/are rejected.								
7)	Claim(s) is/are objected to.								
8)🖂	Claim(s) 1-37 are subject to restriction	n and/or ele	ection requirement.						
Applicati	on Papers								
9)□	The specification is objected to by the	Examiner.							
·			ted or b) objecte	ed to by the E	xaminer.				
,	10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
				<u>*</u>	• •	FR 1.121(d).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.									
Priority ι	ınder 35 U.S.C. § 119								
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).									
a)[a) ☐ All b) ☐ Some * c) ☐ None of:								
	1. Certified copies of the priority documents have been received.								
	2. Certified copies of the priority documents have been received in Application No								
	3. Copies of the certified copies of				d in this National	Stage			
	application from the International Bureau (PCT Rule 17.2(a)).								
* See the attached detailed Office action for a list of the certified copies not received.									
Attachmen	t(s)								
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)									
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application						D-152)			
Paper No(s)/Mail Date 6) Other:									

DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a method to mitigate an allergic response in a patient by enhancing expression of trefoil factor-2 using IL-4, classified in class 424, subclass 85.1.
 - II. Claims 1-10, drawn to a method to mitigate an allergic response in a patient by enhancing expression of trefoil factor-2 using IL-13 classified in class 424, subclass 85.1.
 - III. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6 and small molecule activators, classified in class 514, subclasses 2 and 44.
 - IV. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, small molecule activators and oligonucleotide activators, classified in class 514, subclasses 2 and 44.

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V. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, small molecule activators and transcriptional activators, classified in class 514, subclasses 2 and 44.

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VI. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6 and oligonucleotide activators, classified in classified in class 514, subclasses 2 and 44.

VII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6 and transcriptional activators, classified in classified in class 514, subclasses 2 and 44.

VIII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof

comprising <u>an activator of STAT6, oligonucleotide activators and transcriptional activators</u>, class 514, subclasses 2 and 44.

- IX. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, oligonucleotide activators, transcriptional activators and small molecule activators, class 514, subclasses 2 and 44.
- X. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of a Th2 cytokine and small molecule activators, classified in class 514, subclasses 2 and 44.
- XI. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of a Th2 cytokine, small molecule activators and oligonucleotide activators, class 514, subclasses 2 and 44.

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XII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of a Th2 cytokine, small molecule activators and transcriptional activators, classified in class 514, subclasses 2 and 44.

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XIII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of a Th2 cytokine and oligonucleotide activators, classified in class 514, subclasses 2 and 44.

XIV. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of a Th2 cytokine and transcriptional activators, classified in class 514, subclasses 2 and 44.

XV. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof

comprising an activator of a Th2 cytokine, oligonucleotide activators and transcriptional activators, class 514, subclasses 2 and 44.

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XVI. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of a Th2 cytokine, oligonucleotide activators, transcriptional activators and small molecule activators, class 514, subclasses 2 and 44.

XVII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, an activator of a Th2 cytokine and small molecule activators, class 514, subclasses 2 and 44.

XVIII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, an activator of a Th2 cytokine, small molecule activators and oligonucleotide activators, class 514, subclasses 2 and 44.

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XIX. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, an activator of a Th2 cytokine, small molecule activators and transcriptional activators, class 514, subclasses 2 and 44.

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- XX. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, an activator of a Th2 cytokine and oligonucleotide activators, classified in class 514, subclasses 2 and 44.
- XXI. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, an activator of a Th2 cytokine and transcriptional activators, class 514, subclasses 2 and 44.
- XXII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding

TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, an activator of a Th2 cytokine, oligonucleotide activators and transcriptional activators, class 514, subclasses 2 and 44.

- XXIII. Claims 11-15, drawn to a pharmaceutical composition comprising an effector of trefoil factor-2 expression in a pharmaceutically acceptable formulation and amount sufficient to enhance an amount of DNA encoding TFF2, mRNA encoding TFF2, TFF2 protein, or combinations thereof comprising an activator of STAT6, an activator of a Th2 cytokine, oligonucleotide activators, transcriptional activators and small molecule activators, class 514, subclasses 2 and 44.
- XXIV. Claims 16-21, drawn to a physiological lung assessment method comprising determining a level of trefoil factor-2 in a patient wherein TFF2

 DNA and mRNA are determined, classified in class 435, subclass 6.
- XXV. Claims 16-21, drawn to a physiological lung assessment method comprising determining a level of trefoil factor-2 in a patient wherein TFF2 protein is determined, classified in class 435, subclass 6.
- XXVI. Claims 16-21, drawn to a physiological lung assessment method comprising determining a level of trefoil factor-2 in a patient wherein TFF2

 DNA, mRNA and protein is determined, classified in class 435, subclass 6.
- XXVII. Claim 22, drawn to a prophylactic or therapeutic method for a patient comprising providing trefoil-factor-2 in a pharmaceutically

acceptable composition to a lung of a patient in an amount sufficient to cause reduced lung acidity, classified in class 514, subclass 2.

- XXVIII. Claim 22, drawn to a prophylactic or therapeutic method for a patient comprising providing trefoil-factor-2 in a pharmaceutically acceptable composition to a lung of a patient in an amount sufficient to cause enhanced lung epithelial cell repair, classified in class 514, subclass 2.
- XXIX. Claims 23 and 24, drawn to a treatment method comprising providing to an allergic patient an amount and formulation of a pharmaceutical composition containing at least one compound capable of differentially regulating an allergen-induced gene in a patient, classified in class 514, subclasses 2 and 44.
- XXX. Claims 26 and 28-31, drawn to a method to enhance repair of allergy-induced inflamed tissue comprising administering to a patient a composition comprising a regulator of trefoil factor-2 (TFF2) expression in a pharmaceutically acceptable formulation an in an amount sufficient to up-regulate TFF2 expression to result in reduced acid secretion, classified in class 514, subclasses 2 and 44.
- XXXI. Claims 26 and 28-31, drawn to a method to enhance repair of allergy-induced inflamed tissue comprising administering to a patient a composition comprising a regulator of trefoil factor-2 (TFF2) expression in a pharmaceutically acceptable formulation and in an amount sufficient to

up-regulate TFF2 expression to result in enhanced epithelial cell proliferation, classified in class 514, subclasses 2 and 44.

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- induced inflamed tissue comprising administering to a patient a composition comprising IL-4, a regulator of trefoil factor-2 (TFF2) expression, in a pharmaceutically acceptable formulation and in an amount sufficient to up-regulate TFF2 expression to result in reduced acid secretion, classified in class 424, subclass 85.1.
- induced inflamed tissue comprising administering to a patient a composition comprising IL-4, a regulator of trefoil factor-2 (TFF2) expression, in a pharmaceutically acceptable formulation and in an amount sufficient to up-regulate TFF2 expression to result in enhanced epithelial cell proliferation, classified in class 424, subclass 85.1.
- XXXIV. Claims 27-31, drawn to a method to enhance repair of allergy-induced inflamed tissue comprising administering to a patient a composition comprising IL-13, a regulator of trefoil factor-2 (TFF2) expression, in a pharmaceutically acceptable formulation and in an amount sufficient to up-regulate TFF2 expression to result in reduced acid secretion, classified in class 424, subclass 85.1.
- XXXV. Claims 27-31, drawn to a method to enhance repair of allergy-induced inflamed tissue comprising administering to a patient a

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composition comprising IL-13, a regulator of trefoil factor-2 (TFF2) expression, in a pharmaceutically acceptable formulation and in an amount sufficient to up-regulate TFF2 expression to result in enhanced epithelial cell proliferation, classified in class 424, subclass 85.1.

- 2. Claim 25 links inventions XXX-XXXV. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim, claim 25. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claim are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.
- 3. Groups III-XXIII are different products. Activators of STAT6, small molecule activators, oligonucleotide activators and activators of Th2 cytokines differ with respect to their structures, modes of action, receptors and physicochemical properties; therefore each product is patentably distinct.
- 4. Groups I-II and XXIV-XXXV are different methods. The methods of mitigating allergic response by enhancing expression of trefoil factor-2 using IL-4 or IL-13 of Groups I and II, respectively is different from the prophylactic or therapeutic treatment for a patient comprising providing trefoil-factor 2 in a pharmaceutically acceptable composition to a lung of Groups XXVII and XXIX. The physiological lung assessment

methods of Groups XXIV-XXVI comprising determining a level of trefoil factor-2 in a patient is different from the treatment method of Group XXIX comprising providing to an allergic patient an amount and formulation of a pharmaceutical composition containing at least one compound capable of differentially regulating an allergen induced gene in a patient and from the methods of enhancing repair of allergy-induced inflamed tissue comprising administering to a patient a composition comprising a regulator of trefoil factor-2 expression of Groups XXX-XXXV. Each of these methods is distinct, each from each other, in that the method of each group requires specific ingredients, method steps and endpoints. Therefore, each condition represents patentably distinct subject matter.

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5. Groups III-XXIV / I-II and XXV-XXXV are related as products and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the activators of STAT6, small molecule activators, oligonucleotide activators and activators of Th2 cytokines of Groups III-XXV can be used to stimulate cells in vitro.

These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the

structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Species Election

- 6. Irrespective of whichever group applicant may elect, applicant is further required under 35 U.S.C 121:
- (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable; and
 - (2) to list all claims readable thereon including those subsequently added.
 - A. If any of Groups I or II is elected, applicant is required to elect:
 - 1. a single body part wherein trefoil factor-2 expression is enhanced as recited in claim 5; and
 - 2. a single administration route as recited in claim 7.

The body part species are distinct because each tissue has a different structure, function and protein expression profile that gives the tissue its specific character. The administration routes are distinct because each route has different

ingredients, method steps and endpoints. Therefore, each species is patentably distinct.

B. If any of Groups XXIV-XXVI is elected, applicant is required to elect:

1. a single source of TFF2 for detection as recited in claim 17.

The sample species are distinct because each sample has a different components, source, function and protein expression profile that gives the sample its specific character.

C. If any of Groups XXX-XXXV is elected, applicant is required to elect:

 a single species of trefoil factor-2 expression regulator (transcription factor STAT6 or transcription factor GATA6) as recited in claim 28.

The expression regulator species are distinct because they have different structures, modes of action and physiochemical properties. Therefore, each species is patentably distinct;

2. a single trefoil factor-2 expression regulator (a small molecule activator of STAT6, a STAT6 oligonucleotide or an activator of STAT6 transcription) as recited in claim 29;

The expression regulator species are distinct because they have different structures, modes of action and physiochemical properties;

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3. a single source of inflamed tissue as recited in claim 30; and

The tissue sample species are distinct because each tissue has a different structure, function and protein expression profile that gives the tissue its specific character; and

4. a single condition as recited in claim 31 as being allergic or asthmatic.

The condition species are distinct because each species has a different etiology, pathology and therapeutic endpoint. Therefore, the species represent patentably distinct subject matter.

- 7. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.
- 8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

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12. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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13. Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-

9937. The examiner can normally be reached Monday through Friday from 8:30 am to

5:00 pm. A message may be left on the examiner's voice mail service. If attempts to

reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina

Chan can be reached on (571) 272-0841. The fax number for the organization where

this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

August 25, 2006

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

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Primary